HFA-305

Date of Approval:_____

FREEDOM OF INFORMATION SUMMARY

NADA 141-227

ULCERGARD

omeprazole

For the prevention of gastric ulcers in horses.

Sponsored by:

Merial Ltd.

F0151

Table of Contents

1. GENERAL INFORMATION:

a.	File Number:	NADA 141-227
b.	Sponsor:	Merial Ltd. 3239 Satellite Blvd. Bldg. 500 Duluth, GA 30096-4640 Drug Labeler Code: 050604
c.	Established Name:	omeprazole
d.	Proprietary Name:	ULCERGARD
e.	Dosage Form:	An oral paste containing 37% w/w omeprazole
f.	How Supplied:	The paste comes in a 4-dose oral syringe with individual doses marked 1-4.
g.	How Dispensed:	OTC
h.	Amount of Active Ingredients:	Each syringe contains 2.28 g of omeprazole
i.	Route of Administration:	Oral
j.	Species/Class:	Equine
k.	Recommended Dosage:	One dose per day for up to 28 days in horses weighing 600 to 1200 pounds. Each dose delivers at least 1 mg omeprazole/kg body weight. Horses over 1200 pounds body weight should receive two doses per day.
l.	Pharmacological Category:	Anti-ulcer medication
m.	Indications:	For the prevention of gastric ulcers in horses.

2. *EFFECTIVENESS:*

a. *Dosage Characterization:*

"Studies to Determine the Effectiveness of Omeprazole Oral Paste for the Prevention of Occurrence of Gastric Ulcers in Horses Under Field Conditions" (PR&D 0057301, PR&D 0057302 and PR&D 0057303)

Investigators: Dr. Michèle Doucet, Dr. Gary W. White, and Dr. Roger Sifferman

Study Locations: Centre d'Entraînement Des Chênes – St. Basile le Grand
St. Basile le Grand, Québec, Canada

Centre d'Entraînement Tourigny – Bécancour
Bécancour, Québec, Canada

Les Écuries Alain Durivage (Écuries AD Stable)
Chambly, Québec, Canada

Rex Brooks Training Stables
Vian, OK

Los Alamitos Race Track
Los Alamitos, CA

Blane Schvaneveldt Ranch
Romoland, CA

Animals: Sixty Quarter horses and 35 Standardbred horses (20 males, 20 male castrates and 55 females) ranging in age from 2-6 years with a body weight range of 696-1250 lbs were enrolled. Horses were free of gastric ulcers as confirmed by endoscopy prior to enrollment. Horses were managed in individual stalls and daily training regimen consistent with ulcerogenic conditions throughout the study period. Ninety-two horses completed the study.

Treatment Groups: Within each study, replicates of five horses were formed based on breed, gender, age, location and/or training level. Within replicate, horses were randomly allocated to one of five treatment groups. Group 1 was sham-dosed with an empty syringe from Day 0–27. Group 2 received 1 mg/kg/day omeprazole and Group 3 received 2 mg/kg/day omeprazole from Day 0-27. To evaluate the effect of a loading dose, Groups 4 and 5 were initially given 4 mg/kg/day of omeprazole from Day 0-3. On Day 4-27, Group 4 horses were given omeprazole at 1 mg/kg/day and Group 5 horses were given omeprazole at 2 mg/kg/day.

Route of Administration: Oral

Duration of Study: 28 days

Measurements: The stomach of each horse was examined endoscopically prior to enrollment to confirm that horses were free of gastric ulcers. Follow up endoscopic examinations were conducted on Day ~28. For each horse, the endoscopist recorded a score for the most severe stomach lesions. The following scoring system for gastric ulcers was used:

0 Intact mucosal epithelium (can have reddening and/or hyperkeratosis)
1 Small single or small multifocal lesion
2 Large single or large multifocal lesion
3 Extensive (often coalescing) lesions with areas of apparent deep ulceration

Statistical Methods: All horses were ulcer-free at the beginning of the study (ulcer score = 0). Although horses with observed ulcers on Day 28 were given a score based on ulcer severity, for statistical purposes any horse that scored ≥ 1 was considered a treatment failure and horses that remained ulcer-free on Day 28 (ulcer score = 0) were considered a treatment success.

Study Results:

Table 1. PR&D 0057301, PR&D 0057302 and PR&D 0057303

Treatment	n	Success	Failure
Group 1 Sham-dosed (Days 0-27/28)	17	4 (24%)	13 (76%)
Group 2 Omeprazole 1 mg/kg/day (Days 0-27/28)	19	16 (84%)	3 (16%)
Group 3 Omeprazole 2 mg/kg/day (Days 0-27/28)	18	16 (89%)	2 (11%)
Group 4 Omeprazole 4 mg/kg/day (Days 0-3) 1 mg/kg/day (Days 4-27/28)	19	15 (79%)	4 (21%)
Group 5 Omeprazole 4 mg/kg/day (Days 0-3) 2 mg/kg/day (Days 4-27/28)	19	15 (79%)	4 (21%)

Observations: No adverse events related to omeprazole treatment were reported in these studies. The paste was accepted by all of the omeprazole-treated horses.

Conclusions: Omeprazole given at 1 mg/kg/day for 28 days was as effective as 2 mg/kg/day in the prevention of gastric ulcers in ulcer-free horses. Additionally,

omeprazole given at 1 mg/kg/day for 28 days was as effective in the prevention of gastric ulcers in horses as a regimen that included an initial 4-day loading dose of 4 mg/kg/day followed by 24 days of omeprazole at 1 mg/kg/day. A dose of 1 mg/kg was determined to be the effective dose.

b. Substantial Evidence:

"Studies to Determine the Effectiveness of Omeprazole Oral Paste for the Prevention of Gastric Ulcers in Horses Under Field Conditions"
(PR&D 0048601, PR&D 0048603 and PR&D0048604)

Investigators: Dr. William Bernard, Dr. Gary W. White, and Dr. Scott McClure

Study Locations: Kentucky Training Center
Lexington, KY

Rex Brooks Training Stables
Sallisaw, OK

Dave McShane Racing Stables
Maxwell, IA

Animals: Fifty-six Thoroughbreds and 24 Quarter horses (40 females, 20 males and 20 male castrates) ranging in age from 1-7 years and body weight range of 688-1223 lbs were enrolled. Horses were free of gastric ulcers as confirmed by endoscopy prior to enrollment. Horses were managed in individual stalls and daily training regimens consistent with ulcerogenic conditions throughout the study period. Seventy-seven horses completed the study.

Treatment Groups: Within each study, replicates of two horses were formed based on similarities in age and/or gender. Within each replicate, horses were randomly allocated to receive either sham-dosing with an empty syringe or omeprazole at 1 mg/kg/day from Day 0-27.

Route of administration: Oral

Duration of Study: 28 days

Measurements: The stomach of each horse was examined endoscopically prior to enrollment to confirm that horses were free of gastric ulcers. Follow-up endoscopic examinations were conducted on Day 28 of treatment. For each horse, the endoscopist recorded a score for the most severe stomach lesions. The same gastric ulcer scoring system outlined above in Section 2.a. was used in these studies.

Statistical Methods: All horses were ulcer-free at the beginning of the study (ulcer score = 0). Although horses with observed ulcers on Day 28 were given a score based on ulcer severity, for statistical purposes any horse that scored ≥ 1

was considered a treatment failure and horses that remained ulcer-free on Day 28 (ulcer score = 0) were considered a treatment success.

Results:

Table 2. PR&D 0048601, PR&D 0048603 and PR&D0048604

Treatment	n	Success	Failure
Group 1 Sham-dosed (Days 0-28)	39	4 (10%)	35 (90%)
Group 2 Omeprazole 1 mg/kg/day (Days 0-28)	38	31 (82%)	7 (18%)

Observations: No adverse events related to omeprazole treatment were reported in these studies. The paste was accepted by all of the omeprazole-treated horses.

A combined analysis of the three dose confirmation studies and the three dose determination studies is illustrated in Table 3.

Table 3. Combined analysis

Study	Sham-dosed success	Sham-dosed failure	Sham-dosed Total	Treatment success 1 mg/kg/day	Treatment failure 1 mg/kg/day	Treatment Total 1 mg/kg/day	Total
0048601	2	12	14	11	2	13	27
0048603	0	12	12	10	2	12	24
0048604	2	11	13	10	3	13	26
Combined Dose Confirm-ation	4 (10%)	35 (90%)	39 (100%)	31 (82%)	7 (18%)	38 (100%)	77
0057301	2	4	6	7	0	7	13
0057302	0	6	6	4	2	6	12
0057303	2	3	5	5	1	6	11
Combined Dose Determin-ation	4 (24%)	13 (76%)	17 (100%)	16 (84%)	3 (16%)	19 (100%)	36
Total	8 (14%)	48 (86%)	56 (100%)	47 (82%)	10 (18%)	57 (100%)	113

The primary effectiveness variable for this combined analysis is the binomial variable, presence of ulcers observed. A generalized linear mixed effects model ("glimmix") analysis with a binomial error and a logit link was used. Treatment is a fixed effect. We included block, study and study by treatment as random

effects in our analysis. The glimmix analysis showed that the treatments (sham-dose versus omeprazole) were significantly different at $p<0.0001$.

Conclusions: These data confirm that omeprazole at 1 mg/kg/day for 28 days was effective in the prevention of gastric ulcers in horses exposed to ulcerogenic conditions.

3. *TARGET ANIMAL SAFETY:*

This NADA does not require re-evaluation of target animal safety data. Please refer to the original NADA 141-123 FOI Summary for GASTROGARD (omeprazole) Paste for Horses dated March 16, 1999.

4. *HUMAN SAFETY:*

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for human use. Keep this and all drugs out of the reach of children. In case of ingestion by humans, contact a physician."

5. *AGENCY CONCLUSIONS:*

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that ULCERGARD when used under the labeled conditions of use is safe and effective for the prevention of gastric ulcers in horses.

The drug is available over-the-counter for lay use because a diagnosis of gastric ulcer disease is not required in order to prevent the disease.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. Omeprazole is currently approved for the treatment of gastric ulcers in horses (NADA 141-123) at 4 mg/kg/day. This new approval is based on new dose confirmation study data which establishes the effectiveness of omeprazole at 1 mg/kg/day for the prevention of gastric ulcers in horses.

ULCERGARD is under the following U.S. patent numbers:

U.S. Patent Number	Date of Expiration
5708017	April 4, 2015

6. *ATTACHMENTS:*

Facsimile labeling is attached as indicated below:

Two approved presentations:

A. Traditional-tuck carton with package "outsert" and syringe label

B. Extended-tuck carton with syringe label

MK12797

UlcerGard™

(omeprazole) Oral Paste for Horses

For the prevention of gastric ulcers in horses.

For the prevention of gastric ulcers in horses

Once-a-Day Dosing with a Well-Accepted Paste

Contains 1 Syringe (4 Doses)

NADA 141-227
Approved by FDA

MERIAL

UlcerGard™
(omeprazole) Oral Paste for Horses
For the prevention of gastric ulcers in horses.

1030171600

Product 60019
Contains 1 Syringe (4 Doses)
For the prevention of gastric ulcers in horses

Stomach ulcers can be painful, yet some horses show very few symptoms. Others will lose weight, have recurrent colic, intermittent loose stools, poor hair coat, poor body condition, changes in appetite and/or general poor performance. Once-daily administration of ULCERGARD is recommended in horses exposed to stressful conditions or activities that may induce stomach ulcers in horses. Such conditions may include training, racing, showing, traveling, stall confinement, and competition.

ULCERGARD™ is a trademark of the AstraZeneca Group of Companies.

US Patent: 4255431 and 6706917

1030-1716-00 Rev. 11-2003

Lot No. & Exp. Date

Unvarnished area
1-1/2" w x 1" h

Manufactured by MERIAL LIMITED
2238 Gillhall Blvd., Duluth, GA 30096-4640 USA
Merial Limited, a company limited by shares registered in England and Wales, Registered No. 2322761, with a registered office at PO Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, England, and domesticated in Delaware, USA as Merial LLC.

ACTIVE INGREDIENT: omeprazole

USES: For the prevention of gastric ulcers in horses.

DOSAGE: The minimum recommended dosage is 1 mg/kg per day (0.45 mg/lb) or 1/4 syringe. ULCERGARD has been shown to effectively prevent stomach ulcers in horses exposed to stressful conditions for a duration of 28 days.

WARNINGS: Not for use in humans. Keep this and all medications out of the reach of children. In case of ingestion by humans, contact a physician. Not for horses intended for human consumption. For animal product information call 1-877-MERIAL-E

INFORMATION FOR HORSE OWNERS:

- ULCERGARD is intended for use in healthy horses. If you notice any signs of illness prior to or during the use of this product, consult your veterinarian for appropriate diagnosis and treatment recommendations.
- ULCERGARD may be used in horses that weigh at least 600 lbs. The effectiveness of ULCERGARD in the prevention of gastric ulcers in foals and weanlings has not been evaluated.
- ULCERGARD may be used safely in breeding stallions. Safety in pregnant mares has not been determined.
- Once daily administration of ULCERGARD is recommended in horses exposed to stressful conditions which may include: training, racing, showing, traveling, stall confinement, and competition.
- ULCERGARD is intended for use only in the prevention of gastric ulcers in healthy horses. Clinical signs of gastric ulceration may include anorexia, recurrent colic, intermittent loose stools or diarrhea, poor hair coat, poor appetite, weight loss or poor performance. These signs may also be associated with other diseases as well as existing gastric ulcers. If your horse is exhibiting one or more of these signs, consult your veterinarian for diagnosis and treatment.

STORAGE INFORMATION: Store below 40°F (40°C). Transient exposure to temperatures up to 104°F (40°C) is permitted.

CUSTOMER ASSISTANCE AND WEB SITE: For more information, please call 1-877-MERIAL-E or visit our web site: www.ULCERGARD.com.

READ PACKAGE INSERT FOR FURTHER INSTRUCTIONS AND IMPORTANT INFORMATION.

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2 3/8 | 1 7/8 | 1 131/6 | 1 13/16 | 1 13/16

PREVENTS STOMACH ULCERS BY REDUCING ACID PRODUCTION

Stomach ulcers are more common in horses than once believed. Studies have demonstrated stomach ulcers in over 90% of racehorses and 60% of performance horses in various disciplines. Horses secrete acid in their stomach 24 hours a day. Horses on grass pasture or eating large quantities of roughage infrequently develop stomach ulcers. Horses without continual access to roughage or in rigorous training are at greater risk of stomach ulceration due to the effects of acid on the stomach lining. The additional stresses of traveling, competition, stall confinement, and strenuous exercise can also contribute to the development of stomach ulcers in horses.

ULCERGARD works to prevent stomach ulcers in horses. The active ingredient in ULCERGARD, omeprazole has been extensively tested for safety and

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effectiveness. It works by reducing the production of acid in the horse's stomach. To help horses maintain optimal gastric health, it is recommended that ULCERGARD be administered during stressful events or activities that may induce stomach ulcers. Such conditions may include: training, racing, showing, traveling, stall confinement, and competition.

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Page 3

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DIRECTIONS FOR USE:

Each syringe contains 4 individual daily doses for horses weighing 600-1200 lbs. Please refer to the following dosage chart for help in determining the correct dose for your horse.

ULCERGARD™ DOSAGE CHART

HORSE WEIGHT	DOSE
Less than 600 lbs	Consult a veterinarian
600-1200 lbs	1 dose per day
over 1200 lbs	2 doses per day

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ne to up.

SYRINGE INSTRUCTIONS:

1) To set the syringe plunger, unlock the knurled ring by rotating 1/4 turn and slide the knurled ring along the plunger shaft so that the side nearest the barrel is set at the appropriate daily dose marking. 2) Rotate 1/4 turn to lock ring before dosing. 3) Make sure horse's mouth contains no feed before administration. 4) Remove syringe tip cover. 5) Insert syringe into the corner of the horse's mouth. 6) Depress the plunger until it stops at the knurled ring.

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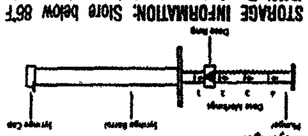
- The entire dose should be deposited on the back of the tongue or deep in the cheek pouch.
- Horses should be observed briefly to assure no part of the dose is lost or rejected.
- If any of the dose is lost, re-dosing is recommended.
- Replace cap if any unused doses remain in the syringe.



STORAGE INFORMATION: Store below 86°F (30°C). Transient exposure to temperatures up to 104°F (40°C) is permitted.

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US Patent: 4255431 and 5708017

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Rev. 10-2003

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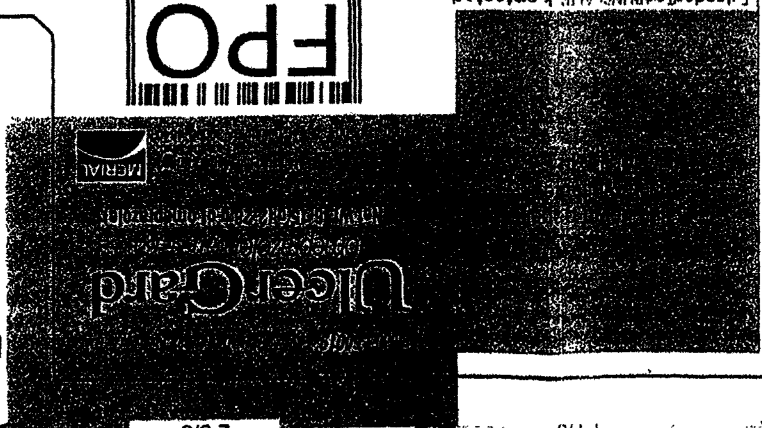

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Front Cover - Pg 1

Front Side of Leaflet

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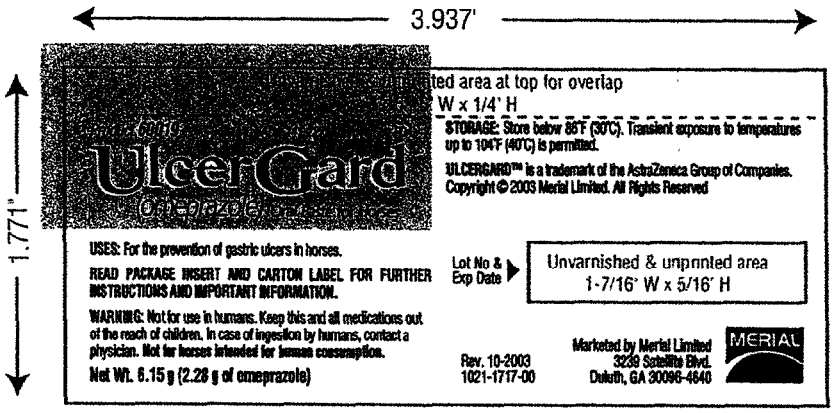
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UlcerGard
omeprazole paste
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STORAGE: Store below 86°F (30°C). Transient exposure to temperatures up to 104°F (40°C) is permitted.
ULCERGARD™ is a trademark of the AstraZeneca Group of Companies.
Copyright © 2003 Merial Limited. All Rights Reserved
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Net Wt. 6.15 g (2.28 g of omeprazole)
Lot No & Exp Date
Unvarnished & unprinted area
1-7/16' W x 5/16' H
Rev. 10-2003
1021-1717-00
Marketed by Merial Limited
3239 Satellite Blvd.
Duluth, GA 30096-4640
MERIAL

CardinalHealth

CUST: Merial

FILE: 7139A

STYLE: Straight tuck

SIZE: 2 x 1 x 9+5/8

SCALE: 1

DATE: 6-Sep-03

Guaymabo PR. 00969

SIDE SHOWN: PRINTED

CUST.DWG.#:

REF.#: 7139A

ACTIVE INGREDIENT: omeprazole

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LIFT FLAP FOR FURTHER INFORMATION

US Patent: 4255431 and 5708017

1030-1719-00 Rev. 11-2003

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Lot No & Exp Date ▼

Unvarnished area
1-1/2" w x 1" h

Marketed by MERIAL Limited
3239 Satellite Blvd., Duluth, GA 30096-4640 USA

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DIRECTIONS FOR USE:
Each syringe contains 4 individual daily doses for horses weighing 600-1200 lbs. Please refer to the following dosage chart for help in determining the correct dose for your horse.

ULCERGARD™ DOSAGE CHART

HORSE WEIGHT	DOSE
Less than 600 lbs	Consult a veterinarian
600-1200 lbs	1 dose per day
over 1200 lbs	2 doses per day

SYRINGE INSTRUCTIONS:

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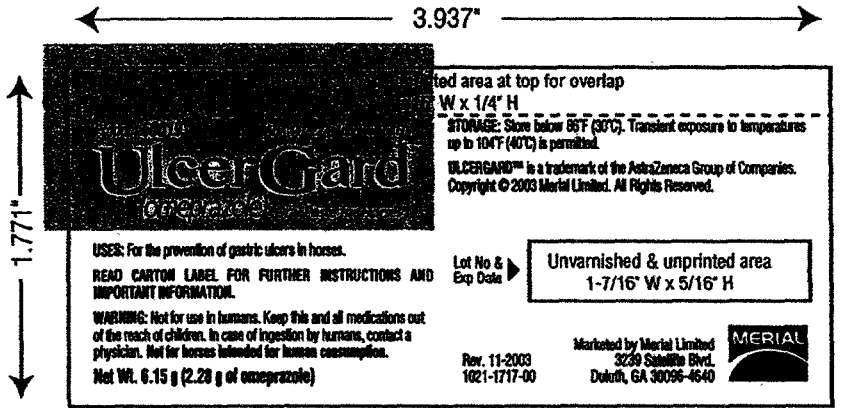
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